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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,811	04/19/2005	Immacolata Coraggio	3687-104	3796

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EXAMINER

KUMAR, VINOD

ART UNIT	PAPER NUMBER
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1638

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<p align="center">Office Action Summary</p>	<p>Application No.</p> <p align="center">10/521,811</p>	<p>Applicant(s)</p> <p align="center">CORAGGIO ET AL.</p>	
	<p>Examiner</p> <p align="center">Vinod Kumar</p>	<p>Art Unit</p> <p align="center">1638</p>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,8 and 15-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,8 and 15-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
|--|---|

DETAILED ACTION

1. Office acknowledges the receipt of Applicant's response filed on October 27, 2006. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 1-3, 8, 15, and newly added claims 16-26 are pending. Claims 1-3, 8, 15, and newly added claims 16-26 are examined in the instant Office action. All previous rejections not set forth below have been withdrawn in view of claim amendments. This action is made FINAL.

Claim Objections

2. Claims 1, 3, 8, 15 and 21 are objected to because of the following informalities:

In claim 1, line 7, replace "stress" at the end of claim with --stresses--.

In claims 1 and 2 replace "(GenBank accession no. Y11414)" with --as set forth in the nucleotide sequence of SEQ ID NO: 1--.

In claims 1, 15 and 21, replace "the" before "OsMyb" with --an--.

In claim 2, line 2, replace "stress" at the end of claim with --stresses--.

In claim 8, line 5, replace "a" after "in" and before "transgenic" with --the--.

In claims 15 and 21, replace "(GenBank accession no. Y11414)" with --as set forth in the nucleotide sequence of SEQ ID NO: 1,--.

In claims 16-20 and 22-26, line 2, insert --a-- before "at least".

Applicant are advised that should claims 15-20 are found allowable, claims 21-26 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both

cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, claims 15 and 21, 16 and 22, 17 and 23, 18 and 24, 19 and 25, and 20 and 26 fall within the same scope.

Appropriate corrections are required.

Claim Rejections - 35 USC § 112

3. Claims 1-3 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection has been necessitated due to claim amendments.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "complementary sequences or transcription products", which is confusing, since it is unclear which complementary sequences and transcription products of OsMyb gene are being referred to. OsMyb gene as set forth in SEQ ID NO: 1 is a cDNA sequence which represents the transcription product. It is unclear what is intended.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "complementary" because it reads on a 2 mer sequence or a different sequence.

Appropriate action/clarifications are required.

Claim Rejections - 35 USC § 112

4. Claims 1-3 and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for while being enabling for a method of producing a stress tolerant transgenic plant comprising transformation of said plant with the OsMyb gene (SEQ ID NO: 1) encoding SEQ ID NO: 2, does not reasonably provide enablement for a method to produce a stress tolerant transgenic plant comprising transformation of said plant with complementary sequences or any transformation products of OsMyb gene other than SEQ ID NO: 1. The claims contain subject matter which was not described in the specification in such a way as to enable any person skilled in the art to which it pertains, with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection has been necessitated due to claim amendments filed on October 27, 2006.

Claim 1 is directed to a method of producing a stress tolerant transgenic plant comprising introducing and expressing complementary sequence(s) of OsMyb gene as defined in SEQ ID NO: 1. The complementary sequence(s) of SEQ ID NO: 1 would either encode no protein or encode a protein which is not identical in sequence to SEQ NO: 2. The specification does not provide guidance how expression of a complementary sequence of SEQ ID NO: 1 in a transgenic plant can impart stress tolerant phenotype to said plant. In the absence of guidance, undue experimentation would have been required by one skilled in the art to determine how to practice the instantly claimed method of introducing and expressing complementary sequences of SEQ ID NO: 1 for imparting stress tolerant phenotype in a transgenic plant.

Claim 1 is directed to a method of producing a stress tolerant transgenic plant comprising introducing and expressing transcription products of OsMyb gene as defined in SEQ ID NO: 1. The specification provides guidance on introducing and expressing SEQ ID NO: 1 (cDNA) in a plant to produce stress tolerant transgenic plant.

Specification does not provide guidance on any other transcription product derived from OsMyb gene sequence that can be used in imparting stress tolerance in a transgenic plant. In the absence of such guidance, undue experimentation would have been required by a skilled artisan to determine how to use any transcription product other than SEQ ID NO: 1 in a method of producing a stress tolerant transgenic plant. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention.

5. Claims 1-3 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection has been necessitated due to claim amendments filed on October 27, 2006.

Claim 1 is directed to a method of producing a stress tolerant transgenic plant comprising introducing and expressing complementary sequence(s) of OsMyb gene as defined in SEQ ID NO: 1. The complementary sequence(s) of SEQ ID NO: 1 would either encode no protein or encode a protein which is not identical in sequence to SEQ

NO: 2. The specification does not have adequate written description for the genus of complementary sequences of OsMyb gene and genus of transcription products of OsMyb gene, under current written description guidelines. Specification does not describe any of these sequences and one skilled in the art would not have reliably predicted the structure of these sequences based upon the disclosure of SEQ ID NO: 1 encoding SEQ ID NO: 2.

Furthermore, said structures of the broadly claimed genus are not correlated to the function of imparting stress tolerance in a transgenic plant. Furthermore, Applicants have failed to describe conserved functional domains that are shared by these undisclosed structures of Applicant's broadly claimed genus. Accordingly, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

6. Claims 1-3, 8 and 15-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Osnanto et al. (Proceedings of the XLV Italian Society of Agricultural Genetics – SIGA Annual Congress Salsomaggiore Terme Italy – 26/29 September, 2001, Examiner's notice of reference cited in the paper mailed December 2, 2005), taken with the evidence of Pandolfi et al. (Plant Physiol., 114:747, 1997) and Solinas et al. (GenBank, NCBI, Sequence Accession No. Y11414, pages 1-2, Published April 1997) for the reasons of record stated in the Office action mailed on July 13, 2006. Applicants traverse the rejection of claims 1-4, 8, 13 and 15 in the paper filed on October 27, 2006.

Applicants argue that Osnanto et al. disclose a method of improving cold tolerance in plants by using the OsMyb gene, and it does not suggest that tolerance to biotic and other abiotic stress would be similarly improved. Applicants further argue that there is no evidence or reasoning presented by the Office action to support the assertion that tolerance to other types of stress would also be improved in Osnanto et al. plants, and thus no case of inherency has been established. Applicants further argue that Pandolfi expressly discloses that treatments different from cold do not lead to the expression of the OsMyb gene, and no correlation existed between other types stresses (anoxia, salt, dehydration, heat) and expression of the OsMyb4 gene (response, page 6, line 23 through the end of 1st paragraph of page 7).

Applicant's arguments were fully considered but were not found persuasive. It is maintained that the property of tolerance to biotic stress, abiotic stresses such as, salt, dehydration, oxidative or osmotic stresses or the property of preventing damages to a

plant due said stresses is inherent to the method of producing the transgenic plant of Osnanto et al. The method steps to produce a cold/freezing tolerant transgenic plant of Osnanto et al. are identical to instantly claimed method steps of producing a stress tolerant transgenic plant. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, rather than any distinct definition of any of the claimed invention's limitations, then preamble is not considered a limitation and is of no significance to claim construction. See MPEP 2111.02. Also see *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1346-48, 64 USPQ2d 1202, 1204-05 (Fed. Cir. 2002) where a claim at issue was directed to a method of preparing a food rich in glucosinolates wherein cruciferous sprouts are harvested prior to the 2-leaf stage. The court held that the preamble phrase "rich in glucosinolates" helps define the claimed invention, as evidenced by the specification and prosecution history, and thus is a limitation of the claim (although the claim was anticipated by prior art that produced sprouts inherently "rich in glucosinolates"). Furthermore, see *Integra LifeSciences I Ltd. V. Merck KGaA* 50 USPQ2d 1846, 1850 (DC Scalif 1999), which teaches that where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then prior art anticipates the claimed invention.

Furthermore, it is important to note the Pandolfi et al. does not indicate or suggest that over-expression of OsMyb4 gene in a transgenic plant would not produce tolerance to salt, dehydration or anoxia. It is important to note the difference between an endogenous expression of OsMyb4 gene (Pandolfi et al. teachings, emphasis

added) under salt, dehydration or anoxia stresses versus the over-expression of OsMyb4 gene in a transgenic plant (Osnanto et al. teachings, emphasis added). The expression of endogenous OsMyb4 gene in response to salt, dehydration or anoxia stress is regulated by its native promoter, whereas, the transgenic plants would constitutively express OsMyb4 gene product to impart tolerance to instantly claimed stresses because said tolerance to biotic or abiotic stresses is an inherently associated property of SEQ ID NO: 1 (OsMyb4 gene) encoding SEQ ID NO: 2. Furthermore, it may also be emphasized that low temperature/freezing tolerance is also a measure of dehydration tolerance.

Accordingly, the rejection is maintained.

7. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Alexandrov et al. (EP 1033405 A2, Published June 9, 2000) for the reasons of record stated in the Office action mailed on July 13, 2006.. Applicants traverse the rejection of claims 1-4, 8 and 14-15 in the paper filed on October 27, 2006

Applicants argue that Alexandrov et al. fail to teach or suggest OsMyb4 gene (response, page 7, lines 9-10).

Applicant's argument was fully considered but not found persuasive. The recitation "complementary sequences" in claim 1 reads on any Myb transcription factor comprising at least 2 mer sequence which is complementary to OsMyb gene as set forth in SEQ ID NO: 1.

Accordingly, Alexandrov et al. anticipate the claimed invention.

8. Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Cahoon et al. (US Patent Publication No. 20020066120 A1, Filed November 19, 1999) for the reasons of record stated in the Office action mailed on July 13, 2006. Applicants traverse the rejection of claims 1-4, 8 and 14-15 in the paper filed on October 27, 2006

Applicants argue that Cahoon et al. fail to teach or suggest OsMyb4 gene (response, page 7, lines 13-14).

Applicant's argument was fully considered but not found persuasive. The recitation "complementary sequences" in claim 1 reads on any Myb transcription factor comprising at least 2 mer sequence which is complementary to OsMyb gene as set forth in SEQ ID NO: 1.

Accordingly, Cahoon et al. anticipate the claimed invention

Conclusions

9. Claims 1-3, 8, 15-26 are rejected.

Applicants amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is set to expire within TWO MONTHS of the mailing date of this final action and the advisory action is

not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

